REMARKS/ARGUMENTS

The examiner has rejected claims 1-14 and 16-21 under 35 U.S.C. § 103(a) as being unpatentable over DeMichele et al. Applicant has carefully considered this rejection but it is most respectfully traversed for the reasons discussed below.

Before discussing the rejection, applicant first wishes to thank the examiner for the courtesy extended to the below signed attorney during the interview on August 14, 2003. The following remarks constitute a statement of the substance of the interview as well as additional comments in support of the patentability of the claimed invention.

The present invention pertains to a fat blend which is built up from components selected from the group consisting of oils, fats, lecithins, fatty acids and salts and esters thereof, and containing polyunsaturated fatty acids, wherein the fatty acids, gamma-linolenic (GLA) stearidonic acid (SDA) and eicosapentaenoic acid (EPA) together comprise 10 to 100 mg per g total fatty acids and the GLA and EPA each comprise 35 to 45 wt. % and the stearidonic acid 15 to 25 wt. % of the sum of these three fatty acids.

The examiner urges in the office action that a *prima facie* case of obviousness is established by the DeMichele reference since this reference teaches overlapping amounts of the aforementioned GLA, SDA and EPA in the same type of fat blend. The examiner indicates that applicant may rebut a *prima facie* case of obviousness based on overlapping ranges by showing the criticality of the claimed ranges (see page 3, lines 3-5 of the final office action). Applicant does not dispute that a showing of the criticality of the claimed ranges is required

to rebut a *prima facie* case of obviousness based on overlapping ranges. However, applicant submits that a *prima facie* case of obviousness has not been established since the DeMichele reference, contrary to the examiner's observation, does not disclose or suggest overlapping ranges of the aforementioned GLA, SDA and EPA.

During the interview the below signed attorney emphasized that the claimed invention is not obvious over DeMichele (the sole reference relied upon by the examiner) since DeMichele does not disclose or suggest the particular combination of fatty acids in the amounts and proportions recited in the claims. In this regard it was pointed out to the examiner that DeMichele prepared lipid blends A-D and subjected these blends to experimentation in order to determine which blends would be useful for treating certain pulmonary disorders. It was emphasized that although some of the blends contain the three fatty acids utilized in applicant's invention, some blends preferred by DeMichele do not include SDA (i.e., blend C).

More importantly, DeMichele does not disclose or suggest a composition which contains the three fatty acids required by applicant's invention in overlapping ranges. In this regard it was pointed out to the examiner that DeMichele states that he conducted various experimental tests on the various lipid blends to determine the amount of the various fatty acids which he requires to practice his invention. In this regard DeMichele notes in the second full paragraph in column 13 as follows:

> In view of the foregoing experimental results and detailed comparisons of various lipid blends it was determined that a liquid nutritional product **in**

> **accordance with the present invention should contain** a lipid blend having a fatty acid profile which has, as a % by weight of total fatty acids, **the amounts of certain selected fatty acids set forth in table 5**. (Emphasis added).

The broadest range in the amount for each of the fatty acids identified in table 5 is set forth in the column under the heading "Preferred Range". Although DeMichele identifies each of the three fatty acids used in applicant's invention, it is clear that the broadest range of stearidonic acid (SDA) utilized by DeMichele is in the range of 0.71-0.97 weight percent with respect to the total fatty acid content of this composition. Table 5 also indicates that the broadest range of GLA is 3.9-5.3 weight percent with respect to the total fatty acid content and the broadest range for EPA is 4.25-5.75 weight percent of the total fatty acid content.

It is clear from the above that DeMichele identifies the minimum and maximum amounts of GLA, SDA and EPA which are permissible for use in his invention. Although the amounts of GLA, SDA and EPA in applicant's claims are given with respect to the sum of only these three fatty acids, it is possible to calculate from the information contained in table 5, the percentage of GLA, SDA and EPA used by DeMichele wherein the percentage is with respect to the sum of only these three fatty acids. In this regard it is to be noted from table 5 that the broadest range of SDA is 0.71-0.97 weight percent based upon the total fatty acid content. The minimum amount of SDA used by DeMichele with respect to the sum of only GLA, SDA and EPA would be 0.71 divided by (5.3+0.71+5.75). The maximum amount of SDA permitted by DeMichele can be calculated by dividing 0.97 by (3.9+0.97+4.25) and converting the calculated amount to the corresponding percentage. **Performing the above calculations reveals that**

DeMichele requires that the SDA must be limited to 6.03-10.63 weight percent with respect to the total sum of GLA, SDA and EPA. In contrast, the claimed invention requires a minimum content of 15 weight % of SDA with respect to the total amount of GLA, SDA and EPA.

In view of the above, it is clear that contrary to the examiner's observation, DeMichele does not disclose a range in the amount of SDA which overlaps the range used by applicant. **In fact, DeMichele limits the amount of SDA to an amount which is far less than the minimum amount required by applicant and accordingly, DeMichele clearly teaches against the range of SDA used in applicant's invention.**

In view of the above, it is clear that DeMichele does not render the invention obvious, and in fact teaches against the claimed invention. The prior art provides absolutely no motivation or suggestion to increase the amount of SDA beyond the maximum amount allowed by DeMichele to arrive at applicant' invention.

During the interview the attached (test report) was discussed. In this regard it is to be noted that the attached test report indicates that the INF-gamma, IL-2 and IL-10 cytokine secretion of stimulated T-cells of healthy volunteers could be influenced by a dietary fat blend containing EPA, STA and GLA in a specific manner compared to a placebo. Thus it is concluded in the test report that the fat blend offers new therapeutic strategies for those diseases in which the immune system is involved.

In view of the above arguments, it is clear that the examiner has failed to establish a *prima facie* case of obviousness and thus the claims are patentably distinguished over the cited art. Accordingly, respectfully requests reconsideration and allowance of all the claims which are currently pending in the application.

Respectfully submitted,
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Test Report

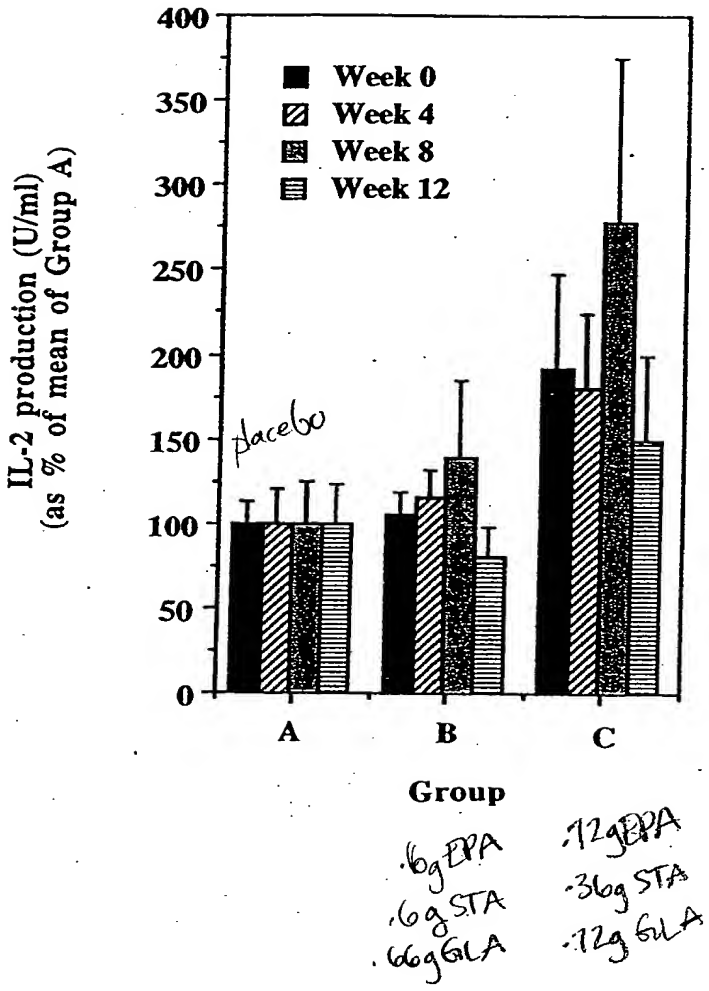
In the pathogenesis of different diseases, like chronic infections, autoimmunity, allergies but also immune deficiency, decreased resistance to infections the dysregulation of the immune response becomes more important. Dietary lipid manipulation may affect different immune parameters. Dihomo-gamma-linolenic acid (DGLA; C20:3n6), derived from Gamma-linolenic acid (GLA; C18:3n6). Stearidonic acid (STA C18:4n3) is a precursor of Eicosapentaenoic acid (EPA, C20:5n3). Both, DGLA and EPA are precursors of the synthesis of eicosanoids such as thromboxanes, prostaglandines and leukotrienes. Eicosanoids are the linkage between fat metabolism and immune system regulation. The intensity of eicosanoids synthesis depends not only on the amount of available precursors, the substrate competition and product inhibition of involved desaturases but also on the activity of the key enzymes lipoxygenase and cyclooxigenase. DGLA, STA and EPA influence the activity of this enzymes.

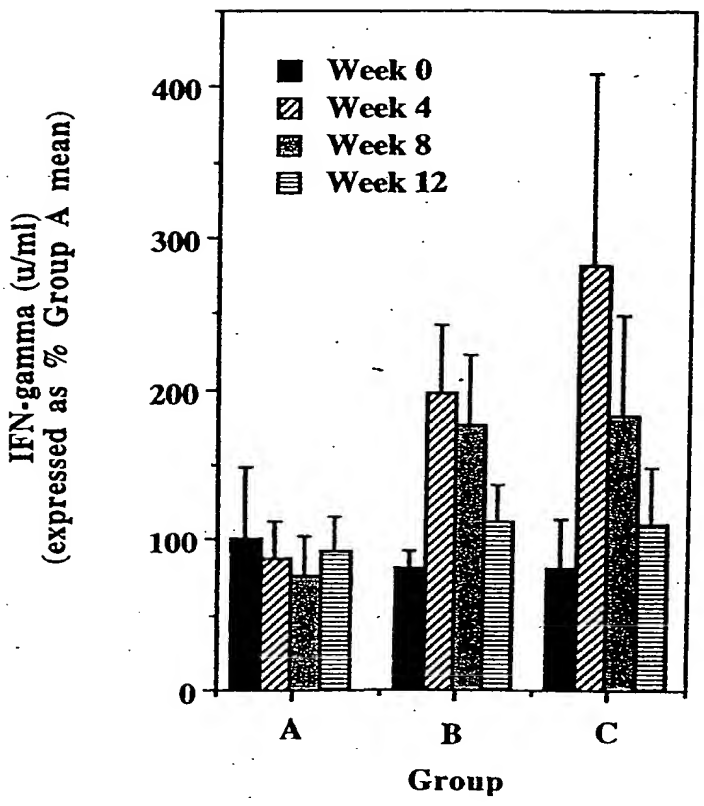
The rationale of this approach is whether it is possible to influence the inflammatory status of healthy volunteers by a dietary fat blend containing EPA, STA, and GLA as part of a dietary supplement to the standard diet. The hypothesis was that this fat blend will change the immunological status of human beings. Therefore an explorative, double blind, randomised, parallel study was designed with healthy volunteers (n=10-12 per group). Three groups (A, B and C) of test persons were used in this test. Each test person received capsules with a fat blend in the amount of 2,5 g/day. A placebo consisting of a 80:20 mix palm oil / sun flower oil was administered to Group A. Group B received an STA-rich oil providing 0,6 g EPA + 0,6 g STA + 0,66 g GLA per day whereas group C received a STA rich oil providing 0,72 g EPA + 0,36 g STA + 0,72 GLA per day.

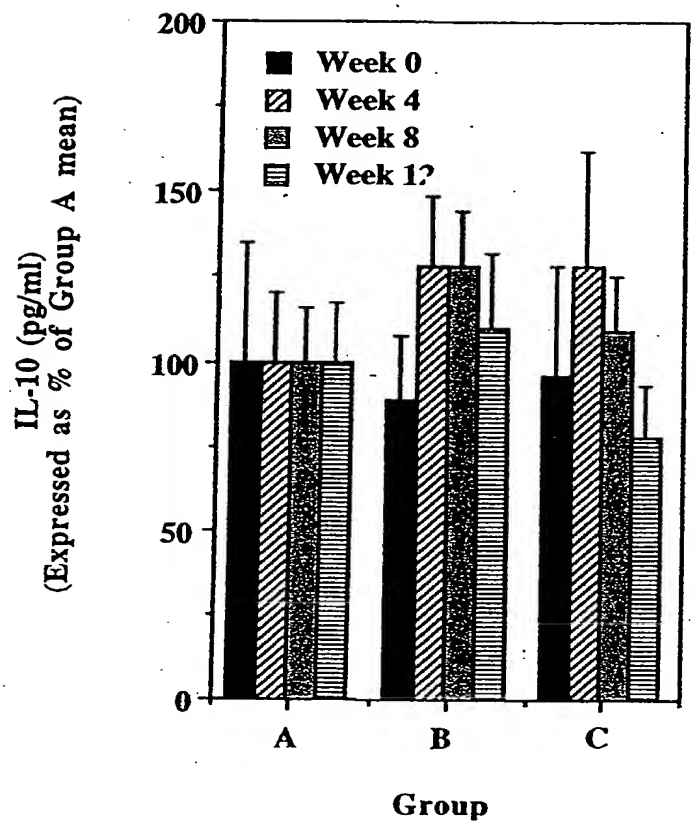
Blood samples of all test persons were taken at week 0, 4, 8 and 12. As can be taken from the attached drafts the fat blends B and C as compared to the placebo (group A) influenced significantly several immunology parameters. As can be seen from the enclosed graphs the fat blends B and C of the present invention caused a significant increase of the cytokine secretion of IL-2, IFN-gamma and IL-10 after mitogenic stimulation of peripheric blood monocytes (PBMC). The immune status of the test persons is therefore improved by orally administering fat blends containing EPA, GLA and STA.

Cytokines are inflammatory mediators and are standard parameters to characterize the immunological status and functionality of immune cells. IL-2 is a cytokine initiating the immune response and a primary growth factor for T-lymphocytes. IFN-gamma is a cytokine initiating the inflammation reaction and causes among others an increase of the activations of macrophages, and an increased MHC expression.
IL-10 is a late cytokine necessary for the regulation of the inflammation reaction. Both messenger substances are formed by T-cells.

This test shows clearly that the INF-gamma, IL-2, and IL-10 cytokine secretion of stimulated T-cells of healthy volunteers could be influenced by a dietary fat blend containing EPA, STA and GLA in a specific manner compared to the placebo. Thus this fat blend offers new therapeutic strategies for those diseases in whose the immune system is involved.


400
350
300
250
200
150
100
50
0
Week 0
Week 4
Week 8
Week 12
IL-2 production (U/ml)
(as % of mean of Group A)
placebo
A
B
C
Group
.6g EPA
.6g STA
.66g GLA
.72g EPA
.36g STA
.72g GLA


Week 0
Week 4
Week 8
Week 12
400
300
200
100
0
IFN-gamma (u/ml)
(expressed as % Group A mean)
A
B
C
Group


200
150
100
50
0
Week 0
Week 4
Week 8
Week 12
IL-10 (pg/ml)
(Expressed as % of Group A mean)
A
B
C
Group